K040215

APR 1 5 2004

510(k) Summary

Trade Name: **Vision-Sciences Flexible Cystoscope with EndoSheath® System**

Sponsor:
Vision-Sciences, Inc.
9 Strathmore Road
Natick, MA 01760
Registration #1223490

Device Common Name:
Cystoscope with sheath

Classification:
According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II.

Predicate Devices:
K031786 – VSI Esophagoscope with Slide-On EndoSheath®
K021344 – VSI Bronchoscope with Slide-On EndoSheath® System
Manufactured by:
Vision-Sciences, Inc.
9 Strathmore Road
Natick, MA 01760
K914008 - Pentax FCY-15P2 Flexible Fiberoptic Cystoscope
K843084 - Olympus CYF-4 Flexible Fiberoptic Cystoscope

Product Description: The device system described in this 510(k) consists of a flexible, fiberoptic cystoscope and sterile, single use protective sheath.

Indications for Use:
The Vision-Sciences Flexible Fiberoptic Cystoscope with EndoSheath® System is indicated for use in endoscopic access and examination of the lower urinary tract including the bladder and, using additional accessories, to perform various diagnostic and therapeutic procedures.

Safety and Performance:
Substantial equivalence for the new device was based on design characteristics, comparison to legally marketed predicate devices, and performance testing. Performance testing included sheath burst/leak testing, sheath tensile/elongation testing, sheathed scope articulation testing, sheathed scope image quality evaluation and scope cycle testing.

Conclusion:
Based on the indications for use, technological characteristics, performance testing and comparison to predicate devices, the proposed VSI Flexible Fiberoptic Cystoscope with EndoSheath® System has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 5 2004

Vision-Sciences, Inc.
c/o Ms. Pamela Papineau, RAC
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
AYER MA 01432

Re: K040215
Trade/Device Name: Flexible Cystoscope with EndoSheath® System
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 FAJ
Dated: January 29, 2004
Received: January 30, 2004

Dear Ms. Papineau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K040215

Device Name: Flexible Cystoscope with EndoSheath® System

Indications for Use:

For endoscopic access and examination of the lower urinary tract including the bladder and, using additional accessories, to perform various diagnostic and therapeutic procedures.

Prescription Use __X___ ~~AND~~/OR Over-the -Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K040215

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